(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 601 338 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **93118002.0**

(51) Int. Cl.5: **A61N 1/05**, A61N 1/39

(22) Date of filing: **05.11.93**

(30) Priority: **11.12.92 SE 9203732**

(43) Date of publication of application:
15.06.94 Bulletin 94/24

(84) Designated Contracting States:
DE FR GB IT NL

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(54) Electrode system for a defibrillator.

(57) An electrode system for a defibrillator. The electrode system provides, without a ventricular electrode, efficient utilization of the energy stored in the defibrillator combined with favorable distribution of current in the heart. The electrode system consists of three electrodes, at least two of which intravascular (12, 18). One of these electrodes (12) is placed in the inferior vena cava (6) and the second is placed in the coronary sinus (8) including its prolongation along the base of the heart. The third electrode consists either of an extravascular patch electrode (17) located in the region of the left ventricle or of an additional intravascular electrode (14) located in the superior vena cava (2). The intravascular electrodes (12, 14, 18) are devised so they do not impede the flow of blood in the vein in which they are located.

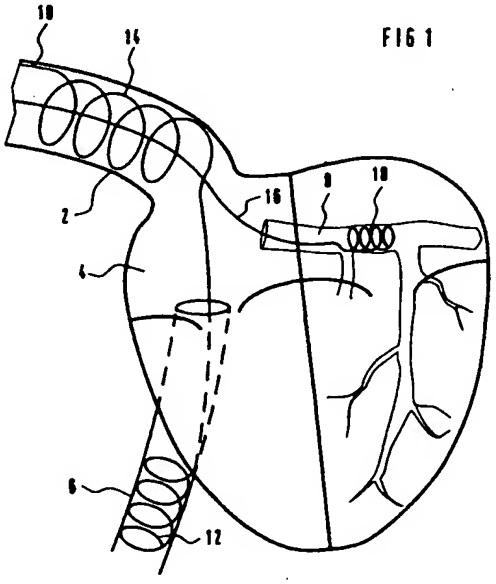


FIG 1

EP 0 601 338 A1

This invention relates generally to an electrode system intended for proximal connection to a cardioverter/defibrillator and for distal placement in the heart region to deliver electrical energy from the cardioverter/defibrillator to the heart so an arrhythmia in the heart can be terminated. More specifically, the invention relates to a system with three electrodes, at least two of which intravascular as stated in the preambula of claim 1.

In defibrillation/cardioversion ("cardioversion" in this context refers to defibrillation using lower energy; the collective designation "defibrillation" will henceforth be used below) using a three-electrode system with two intravascular electrodes, one of the intravascular electrodes is normally placed in the right ventricle and the other either in the superior vena cava or, less commonly, in the inferior vena cava or even in the coronary sinus and its prolongation along the base of the heart. The third electrode is arranged as a subcutaneous electrode with a large area, i.e. a patch electrode, for the purpose of achieving efficient utilization of the energy stored in the heart and good distribution of current in the heart while simultaneously avoiding major surgery (opening of the thorax). The subcutaneous patch electrode is usually placed in the vicinity of the left ventricle between the patient's thorax and skin.

Electrode systems with the above-described locations are shown among a plurality of others in US-A-4 708 145. In addition to the intravascular electrodes shown there with a common electrode cable for a plurality of electrodes in the right ventricle and superior vena cava, separate electrode cables for different electrodes, as well as a separate sensing electrode for detecting cardiac events, are also possible. This is shown in US-A-4 727 877, EP-A-0 373 953 and US-A-5 044 375 respectively.

A common feature of placements in the prior art systems is an electrode in the right electrode. However, such an endocardiac electrode, shown in the applicant's previous application, EP 92 104 098, applicant reference GR 92 P 7303, imposes strain on the heart in the form of irritation of the musculature of the heart wall and the valves between the atrium and ventricle. There is a concomitant increased risk of blood clot formation. So the previously cited application proposed an electrode placement in which the endocardiac electrode is avoided and replaced by an electrode in the inferior vena cava.

The purpose of the invention is to achieve an electrode system, without the ventricular electrode, in which efficient utilization of the energy stored in the defibrillator is combined with favorable distribution of current in the heart.

This purpose is achieved with an electrode system of the above-described type with the features specified in patent claim 1.

With a design according to the invention, a three-electrode system is therefore attained, without a ventricular electrode, for defibrillation with at least two intravascular electrodes, one of which placeable in the coronary sinus including its prolongation along the base of the heart.

In the advantageous embodiments according to the invention described in the sub-claims, at least some of the venous electrodes can be arranged along a common electrode cable and/or have means for fixation to the inner venous wall. The fixation means can be in the form of a hollow, resilient cylinder, fixation being achieved through the cylinder's radial expansion. The hollow cylindrical shape of the electrode enables blood to flow unimpeded through the electrode. Other advantageous embodiments are also described in the sub-claims.

The electrode system according to the invention will be described below, referring to an attached drawing in which

FIG. 1 schematically shows a cross-section of a heart (frontalplane) with the electrode system connected to the heart according to a first embodiment of the invention; and

FIG. 2 schematically shows a cross-section of a heart (frontal plane) with the electrode system connected to the heart according to a second embodiment of the invention.

Identical reference designations designate the same or similar parts in the FIGURES. In FIG. 1 and 2, hidden electrode parts in the inferior vena cava and the vein itself are dashed.

FIG. 1 shows a cross-section of a heart and a number of vessels of relevance to the invention. A first electrode cable 10 is introduced through the superior vena cava 2, passes through the right atrium 4 and exits into the inferior vena cava 6. At its distal end, the cable 10 bears an electrode 12 anchored in the inferior vena cava (6). The cable also has an additional electrode 14 anchored in the superior vena cava 2 proximal to the electrode 12. A second electrode cable 16 is also introduced through the superior vena cava 2 but passes through the right atrium 4, in contrast to the cable 10, in such a way that it exits into the coronary sinus 8 and its prolongation, the great cardiac vein, along the base of the heart. At its distal end, the cable 16 bears an electrode 18 anchored in the coronary sinus/great cardiac vein 8. The electrode 18 is connectable to the defibrillator by a conductor present in the cable 16. The electrodes 12 and 14 are also individually connectable to the defibrillator by separate conductors present in the cable 10.

The electrode system according to FIG. 2 differs from the system shown in FIG. 1 by replacement of the electrode 14 sited in the superior vena cava 2 with a subcutaneous patch electrode 17 near the left ventricle 7, the patch electrode connectable to the defibrillator by an existing conductor in the cable 19. Here, "subcutaneous placement" means placement between the thorax (including the ribs) and skin. The defibrillator's enclosure can alternately be used as a patch electrode.

Connection of the electrodes to the defibrillator according to FIG. 1 and FIG. 2 and between one another can be achieved in different ways. For example, the electrodes 14, 18 in FIG. 1 can be interconnected so the defibrillation impulse is emitted between these electrodes, on the one hand, and the electrode 12 in the inferior vena cava 6, on the other hand. In the corresponding manner, the electrodes 17, 18 in FIG. 2 can be interconnected so the defibrillation pulse is emitted between these electrodes, on the one hand, and the electrode 12, on the other hand.

However, the electrodes 12, 14, 18 and 12, 17, 18 respectively can be interconnected in such a way that the defibrillation pulse is emitted between another one of these electrodes, on the one hand, and the other two electrodes, on the other hand. Alternately, the electrodes 12, 14, 18 and 12, 17, 18 respectively can be supplied with different defibrillation voltages or, as an additional alternative, pairs can deliver defibrillation pulses sequentially. Mono-, bi- or multiphasic defibrillation pulses can be used.

The cable 10 shown in FIG. 1 common to the two electrodes 12, 14 can be replaced with separate electrode cables for these two electrodes 12, 14. Introduction through the inferior vena cava 6 can be an alternative for the described introduction of intravascular electrodes through the superior vena cava 2. The intravascular electrodes can have a common electrode cable or separate electrode cables also in the latter introduction route. Thus, the electrodes 12, 18 can alternately have a common electrode cable in the configurations shown in both FIG. 1 and FIG. 2.

The described electrode configurations can also be complemented with a separate stimulation/sensing electrode for stimulating/sensing cardiac events and/or a sensor for different parameters related to e.g. cardiac hemodynamics. The sensing electrode cable can also contain a stimulation electrode for pacing functions.

The intravascular electrodes 12, 14, 18 are kept in place in the respective vein by being constructed in a way making them radially expandable, then forming at least the contours of a hollow cylinder in the expanded state. Defibrillation electrodes of this type are described in detail in the applicant's simultaneously filed patent application entitled "Defibrillation electrode", applicant reference GR 92 P 7364, this reference forming a part of the present application so as to avoid repetition. The intravascular electrodes 12, 14, 18 are therefore e.g. kept in place in the respective vein by being shaped in the form of helices which apply pressure to the inner wall of the vein by being biased perpendicular to the longitudinal axis of the helix. To avoid repetition, only helical fixation of the electrode 12 in the inferior vena cava 6 will henceforth be described, but the description obviously covers other intravascular electrodes. In its preshaped state, the helical electrode 12 can be envisaged as being coiled around an imaginary cylinder whose external diameter is somewhat larger than the caliber of the inferior vena cava 6. The helix can be made of an electrically conductive, biocompatible material. The electrode 12 is connected to the electrode cable 10 in such a way that they jointly form a single unit. A centrally arranged longitudinal channel through which a stylet can be introduced runs through the electrode 12 and electrode cable 10. In implantation, the electrode 12 is straightened out with the aid of the stylet, the diameter of the electrode 12 thereby becoming smaller than the diameter of the blood vessels it is to traverse and enabling it to be advanced into the inferior vena cava 6. When the implanting physician has decided on an appropriate site for the electrode 12 in the inferior vena cava 6, the stylet can be withdrawn, causing the electrode 12 to resume its preshaped helical configuration. The pressure of the helix against the venous wall keeps the helix in the desired position. In the affixed position, the electrode 12 forms a relatively large electrode surface pressing on the vascular wall. At the same time, the helical electrode 12 has the advantage of enabling blood in the vessel to flow unobstructed through the interior of the helix. The risk of clot formation is thereby minimized. The electrode 12 can also be readily repositioned by reintroduction of the stylet into the central channel to straighten out the electrode 12. The implanting physician can therefore easily find a site for the electrode 12 which, with the other electrodes, achieves a favorable distribution of current in heart tissue.

In implantation, the physician can employ an introductory catheter instead of a stylet. The electrode cable 10 with the straightened electrode 12 is inserted into the introductory catheter, the latter being sufficiently stiff to keep the electrode 12 straightened out during implantation. When the electrode 12 has been advanced to the desired position in the inferior vena cava 6, the introductory catheter can be withdrawn so the electrode resumes its preformed configuration.

In instances in which the electrodes are located on a common electrode cable, e.g. electrodes 12, 14 in FIG. 1, the implantation can be performed with the aid of a single stylet in a central channel running along the length of the electrodes 12, 14 and the catheter 10. Both electrodes 12 and 14 are then straightened out for implantation. When the electrode 12 has reached the desired position, the stylet is withdrawn enough for the electrode 12 to resume its helical configuration. The electrode 14 is then positioned at the desired site in the superior vena cava 2. When the electrode 14 is in the correct
position, the stylet is completely withdrawn so the electrode 14 also resumes its original, preshaped configuration. An introductory catheter can also be used instead of the stylet.

The electrode 18 intended for location in the coronary sinus 8 and its prolongation along the base of the heart can consist of e.g. two sub-electrodes placed in the coronary sinus 8 and its prolongation respectively. The two sub-electrodes can be arranged on a common prolongation of e.g. the electrode cable 16. The two sub-electrodes are placed in the coronary sinus 8 and its prolongation in such a way that an individually adapted, additionally improved distribution of current in the heart is achieved. Here, implantation is performed in the same way as described above. More than two sub-electrodes can be used.

LIST OF REFERENCES

2	Superior vena cava
4	Right atrium
6	Inferior vena cava
8	Coronary sinus
10, 16, 19	Electrode cable
7	Left ventricle
12, 14, 18	Electrodes
17	Patch electrode

Claims

1. An electrode system for a defibrillator with three electrodes, at least two (12, 18) of which being intravascular and one (12) of said at least two electrodes adapted to be placeable in the inferior vena cava (6), the third electrode consisting either of a patch electrode (17) placeable in the region of the left ventricle (7) or of an additional intravascular electrode (14) adapted to be placeable in the superior vena cava (2), wherein the second (18) of the at least two electrodes (12, 18) is adapted to be placeable in the coronary sinus (8) including its prolongation along the base of the heart.

2. An electrode system of claim 1, wherein at least two, of the electrodes (12, 14, 18) intended for placement in the inferior vena cava (6), superior vena cava (2) the coronary sinus (8) including its prolongation along the base of the heart respectively, are arranged on a common electrode cable.

3. An electrode system of claim 1 or 2, wherein the intravascular electrodes (12, 14, 18) in the electrode system have means for affixation to the inner wall of the vein in which they are sited.

4. An electrode system of claim 3, wherein the fixation means is achieved when the electrode (12, 14, 18) in the affixed position has the shape of hollow, resilient cylinder whose diameter exceeds the diameter of the vein enough for the electrode to press against and affix the electrode to the inner wall of the vein.

5. An electrode system of claim 4, wherein the electrode consists of a helix whose windings form at least part of the cylinder's mantle surface.

6. An electrode system of any of the above claims, wherein the patch electrode (17) can consist at least in part of the defibrillator's enclosure.

7. An electrode system of any of the above claims, wherein the electrode intended for placement in the coronary sinus (8) and its prolongation along the base of the heart consists of at least two sub-electrodes, the distal of the at least two sub-electrodes being connected to the proximal sub-electrode by a prolongation of the electrode cable (16), the sub-electrodes being placeable at separate sites on the coronary sinus (8) including its prolongation along the base of the heart.

FIG 1

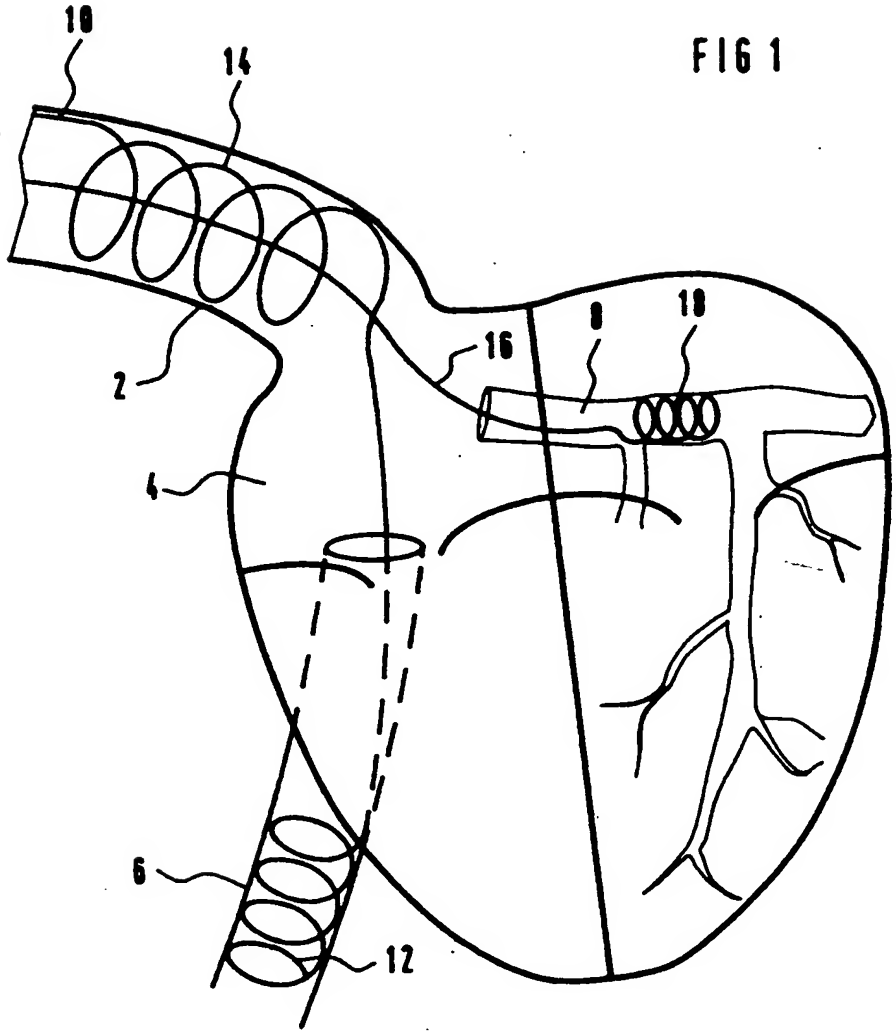
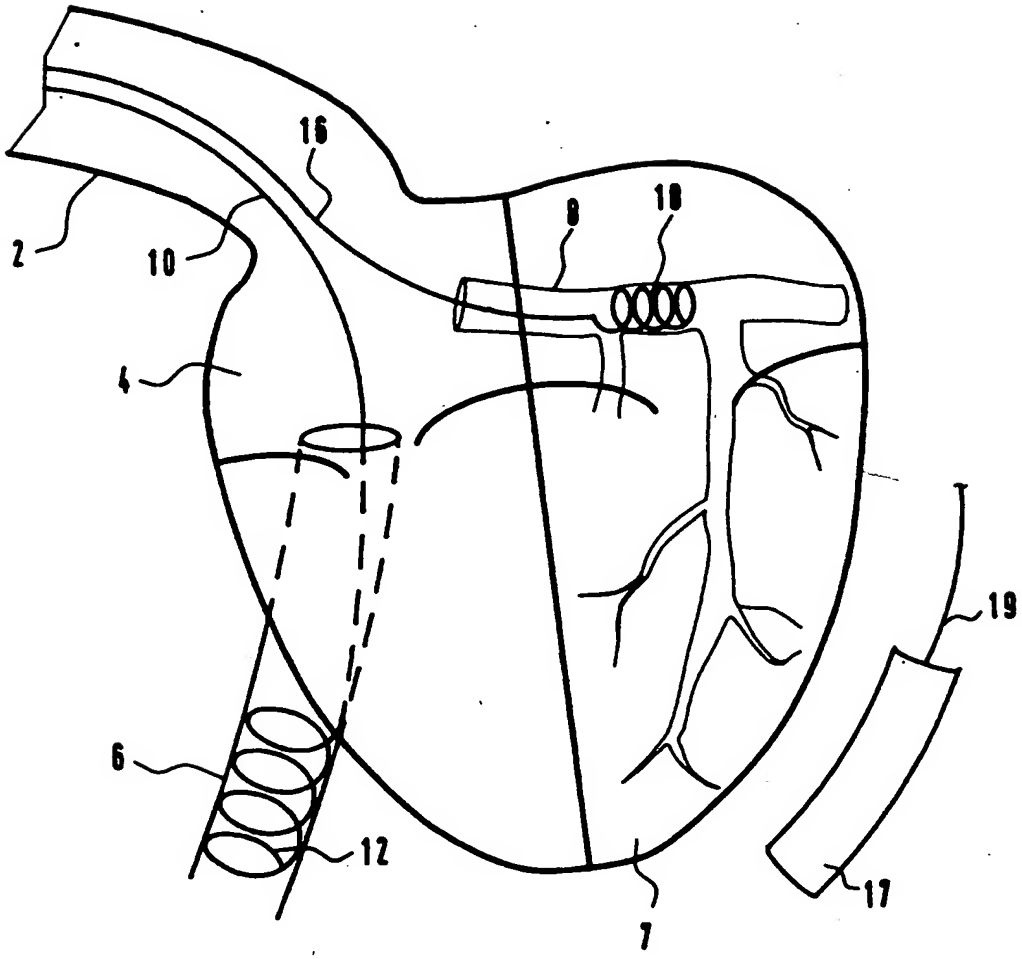


FIG 2



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EUROPEAN SEARCH REPORT

Application Number
EP 93 11 8002

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
A	US-A-5 014 696 (RAHUL MEHRA) * column 5, line 56 - line 64 * * column 6, line 60 - column 7, line 20; figures 5C,7A *	1,7	A61N1/05 A61N1/39
A	WO-A-92 11898 (MEDTRONIC INC.) * page 2, line 24 - page 4, line 4; figures 1-4 * * abstract *	1,3-5	

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	4 March 1994	bengtsson

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
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